

	<b>Regulatory Standards Division AMA-200</b>	<b>Document #</b>  WI 214.02	<b>Revision</b>  1
<b>Title:</b> Product Development Planning Work Instruction			<b>Page 1 of 4</b>

REVISION HISTORY			
Rev	Description of Change	Author	Effective Date
A	Original	JLA	06/03/2003
1	Update Form and Document Numbers	JLA	01/21/04

REFERENCE DOCUMENTS	
Document Number	Document Title
<a href="#">QMS 200</a>	AMA-200 Quality Systems Manual
<a href="#">QP 214</a>	Product Development Procedure

Documents referenced in this work instruction are applicable to the extent specified herein.

## 1. Purpose

This work instruction describes the development of a draft plan for the design and deployment of a customer requested project.

## 2. Scope

This work instruction applies to the planning stage of the Product Realization Procedure.

## 3. Definitions and Acronyms

See the [QMS 200](#) and [QP 214](#)

## 4. Flowchart


There is no flowchart required for this document.

## 5. Responsibilities

5.1 The **Project Coordinator** (PC) shall:


- 5.1.1 Coordinate with the appropriate AMA-200 personnel, product lines and the customer.
- 5.1.2 Develop the Draft Plan.
- 5.1.3 Communicate plan development status.
- 5.1.4 Incorporate all approved changes to the Plan.

5.2 Project team members shall assist the Project Coordinator.


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## 6. Work Instructions

- 6.1 The PC should develop the draft plan in coordination with the project team members.
- 6.2 Review the following documents:
  - 6.2.1 Customer Request Document
  - 6.2.2 Evaluation of Customer Request
  - 6.2.3 Project Overview Statement
  - 6.2.4 Previous planning if this is a resubmitted customer request
- 6.3 The following items should be considered in the development of the draft plan:
  - 6.3.1 A detailed statement of the customer request
    - 6.3.1.1 The statement should include the scope, purpose, and outcome of the project
  - 6.3.2 A time line for the project including the projected delivery date
  - 6.3.3 Develop a schedule of events that reflects project milestones, goals, objectives and deliverables.
  - 6.3.4 Status reporting requirements
  - 6.3.5 Communication Plan
    - 6.3.5.1 Internal, within AMA-200
    - 6.3.5.2 With the customer via the POC, relating to:
      - 1. Product information
      - 2. Questions, agreements, and when applicable, amendments
      - 3. Customer feedback, including complaints
    - 6.3.5.3 Collection and distribution structure
    - 6.3.5.4 Types of information to be disseminated
  - 6.3.6 Changes to the plan
    - See Plan Change Request Work Instructions ([WI 214.04](#)).
  - 6.3.7 Resources
    - 6.3.7.1 Automation requirements and compatibility
    - 6.3.7.2 Administrative support

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- 6.3.7.3 Specialized training requirements project team members, customer, and/or intended users
- 6.3.7.4 Contractor support and availability
- 6.3.7.5 Subject Matter Expert requirements and availability
- 6.3.7.6 Facilitator requirements and availability
- 6.3.7.7 PAACE representation requirements and availability if required.
- 6.3.7.8 Logistics
  - 6.3.7.8.1 Location where the project will be developed
  - 6.3.7.8.2 Facilities required, e.g. hotels, conference rooms, etc.
  - 6.3.7.8.3 Material support
  - 6.3.7.8.4 Transportation
- 6.3.7.9 List resources outside of AMA-200 that may be required
- 6.3.8 Select the best methodology for the Execute Plan process
- 6.3.9 Identify stakeholders
- 6.3.10 Development of Users Manual, if required
- 6.3.11 Coordination for access to applicable documents and standards, if required
- 6.3.12 Requirements for interface with current infrastructure or existing projects, if needed
- 6.3.13 State the scope of the verification process
  - 6.3.13.1 Identify a verification process that ensures the product meets the specific requirements in the Plan.
  - 6.3.13.2 Resource requirements for verification
- 6.3.14 State the scope of the validation process
  - 6.3.14.1 Identify a validation process that ensures the Product is capable of meeting the requirements for the specified application or intended use.
  - 6.3.14.2 Identify the resource requirements for validation
- 6.3.15 Post delivery requirements
- 6.3.16 Implementation guidelines (who and how?)

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- 6.4 After the draft plan is complete, it will be forwarded through the Assigned Branch Manager to the Leadership Team for approval.
- 6.5 If the Leadership Team does not approve the draft plan, it is returned to the PC for correction.
  - 6.5.1 After correction the draft plan is resubmitted to the Leadership Team for approval.
- 6.6 If the draft plan is approved by the Leadership Team, it is forwarded to the PC to initiate the Execute Plan process.

## 7. Metrics

There are no metrics required for this document.

## 8. Quality Records

Quality Records for this document are listed in the table below. These records shall be generated and managed in accordance with AMA-200 Quality Records procedures.

Verifying Document Type or Number	Title	Retention Time
<a href="#">QF 210</a>	Document Change Request (DCR)	Five Years

Quality forms are found in Appendix 1 of the AMA-200 QMS.